The Complete Guide to Direct-To-Consumer Lab Testing

LEGAL, REGULATORY, AND CLINICAL CONSIDERATIONS FOR VIRTUAL TESTING PROGRAMS

wheel

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Explosive growth & patient empowerment

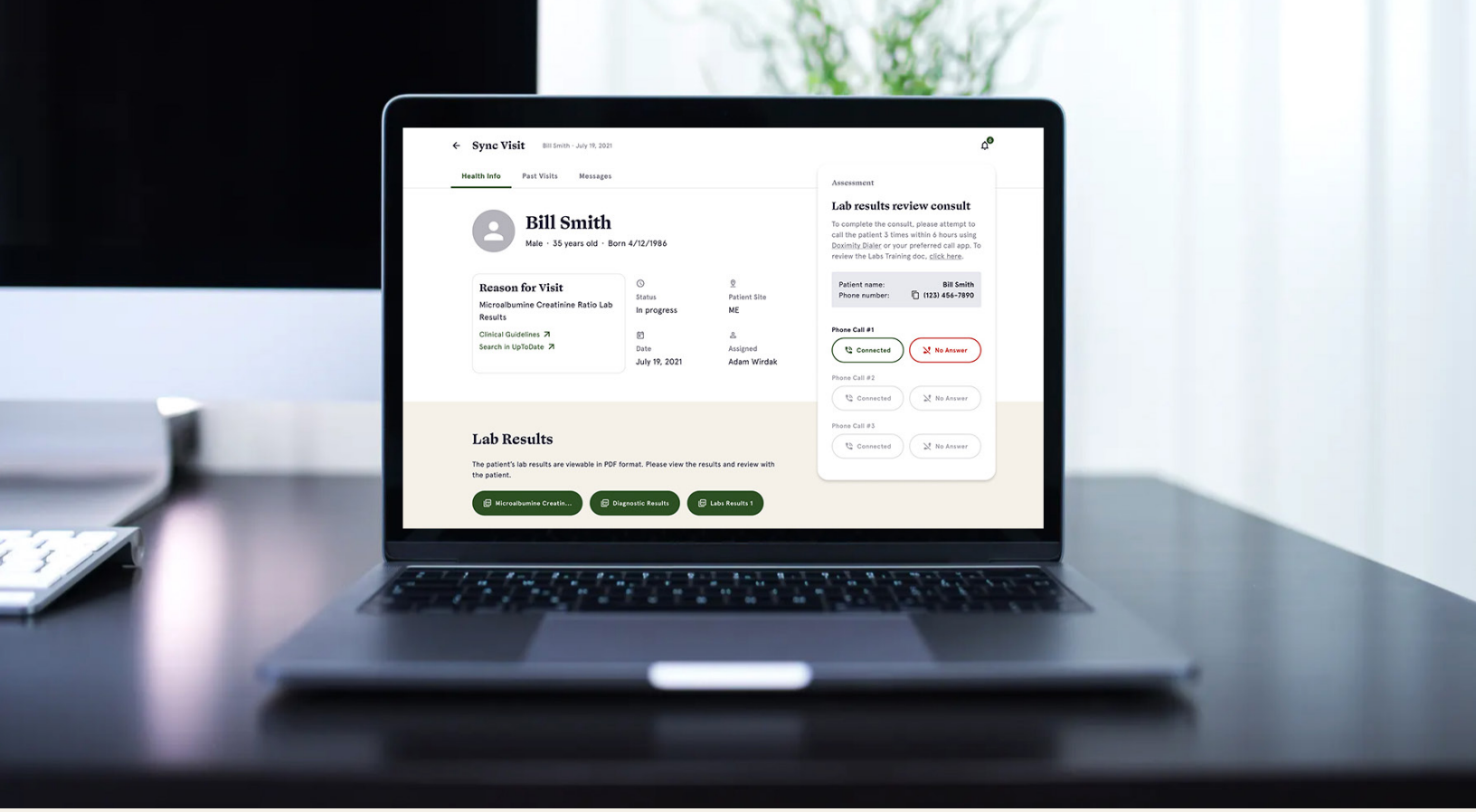
The rise of patient-consumerism has flipped the concept of diagnostic testing on its head. As patients increasingly adopt a self-service healthcare mentality, the popularity of direct-to-consumer (DTC) lab testing has grown exponentially over the past few years.

In fact, it's estimated that the global market for DTC lab services will double in the next few years from a reported 1.4 billion in 2020 to 2.4 billion by 2025. (BCC Research)

It's no wonder that digital health companies and labs themselves are clamoring for a piece of the diagnostic pie.

As health and wellness companies look to offer consumer-initiated testing, there are critical legal, regulatory, and clinical considerations that stakeholders must take into account to ensure a safe and compliant lab service offering.

Here, we'll dig into the consumer lab testing market, review lab test regulation requirements, and outline the clinical capabilities required for an effective program.



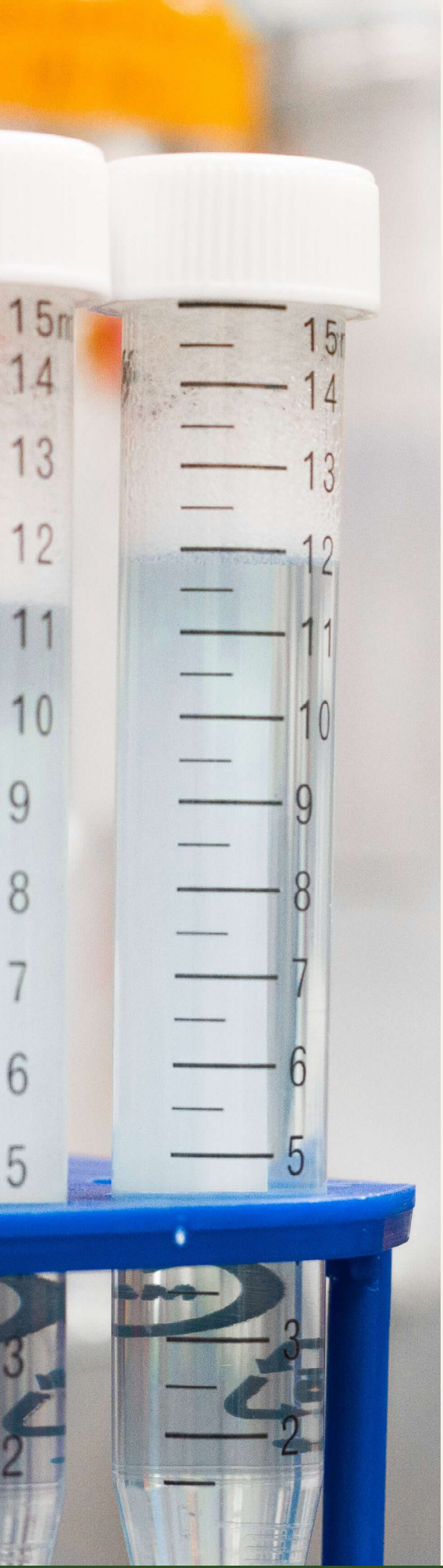
Intro to the DTC lab testing market

The global pandemic accelerated the adoption of virtual care, and more recently, ushered at-home testing into people's daily lives with readily available COVID test kits. Before COVID, genetic testing led the way, with companies like 23andMe and Counsyl capitalizing on curiosity about our ancestry and genetic makeup.

Today, consumers can access a myriad of testing kits for general wellness, men's and women's health, food or allergen sensitivities, STIs, and more.

Motivations driving adoption of at-home lab testing:

- Privacy or stigma
- Ownership over health data
- Convenience
- Cost savings
- Self-empowerment in managing health
- Rapid turnaround time
- Early disease detection
- Second opinions
- Access to tests that aren't covered by insurance



DAT and IVDs

What is direct access testing (DAT)?

Direct-to-consumer lab testing is also known as direct access testing, patient-initiated testing, or consumer-directed testing. Rather than a clinician ordering a test for a patient, individuals can purchase a lab test directly from a digital health or lab company online, paying for the test up-front.

It should be noted that some states do not allow for DAT without prior consultation with a clinician or a clinician's authorization. This means companies interested in offering nationwide services must partner with clinicians for testing oversight in the states with limitations or prohibitions on DAT.

What is an in vitro diagnostic test (IVD)?

IVDs are clinical tests that analyze samples like blood, urine, or saliva to diagnose conditions, guide treatment decisions, or mitigate/prevent future disease. IVDs measure the presence of certain substances, the absence of specific markers, or an immune response to an infection.

An IVD can be a DTC test, and it's an important category to understand for regulatory purposes.

Regulations for DTC Lab Testing

FDA LAB TESTING REVIEWS

In the United States, IVD tests for the commercial market are regulated by the FDA to ensure safety and effectiveness. Technically, the FDA categorizes these tests as medical devices.

Medical devices, and therefore in vitro diagnostic tests, are categorized based on risk, with tests falling into one of three categories (Class I - Class III). The testing category determines the level of oversight the FDA has over the test's accuracy.

"In general, direct-to-consumer tests for non-medical, general wellness, or low-risk medical purposes are not reviewed by the FDA before they are offered. Direct-to-consumer tests for moderate to high-risk medical purposes, which may have a higher impact on medical care, are generally reviewed by the FDA to determine the validity of test claims." - FDA.gov

Whether or not a particular test requires FDA review, companies still must generally register with the agency, list the products to be commercially distributed, and make those products according to Quality Systems Regulations unless an exemption applies.

It's important for companies looking to market consumer tests to understand the differences in each FDA classification and where their products fall to determine the upfront requirements for compliance.

Learn more about FDA oversight for DTC lab tests here.

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA reviews include:

- Analytical validity: Whether a test can accurately and reliably measure what it claims to measure
- Clinical validity: Whether the measurement is predictive of a certain state of health
- Claims: What a company says about their test and how well it works

Diagnostic labs and CLIA

All labs performing direct-to-consumer testing must have an appropriate CLIA certification (Clinical Laboratory Improvement Amendments), among other state and local requirements. CLIA certification is enforced by the Centers for Medicare and Medicaid Services (CMS) to ensure quality control.

Digital health companies interested in partnering with a lab for test analysis should ensure the lab is CLIA-certified. The CDC provides a searchable database here.

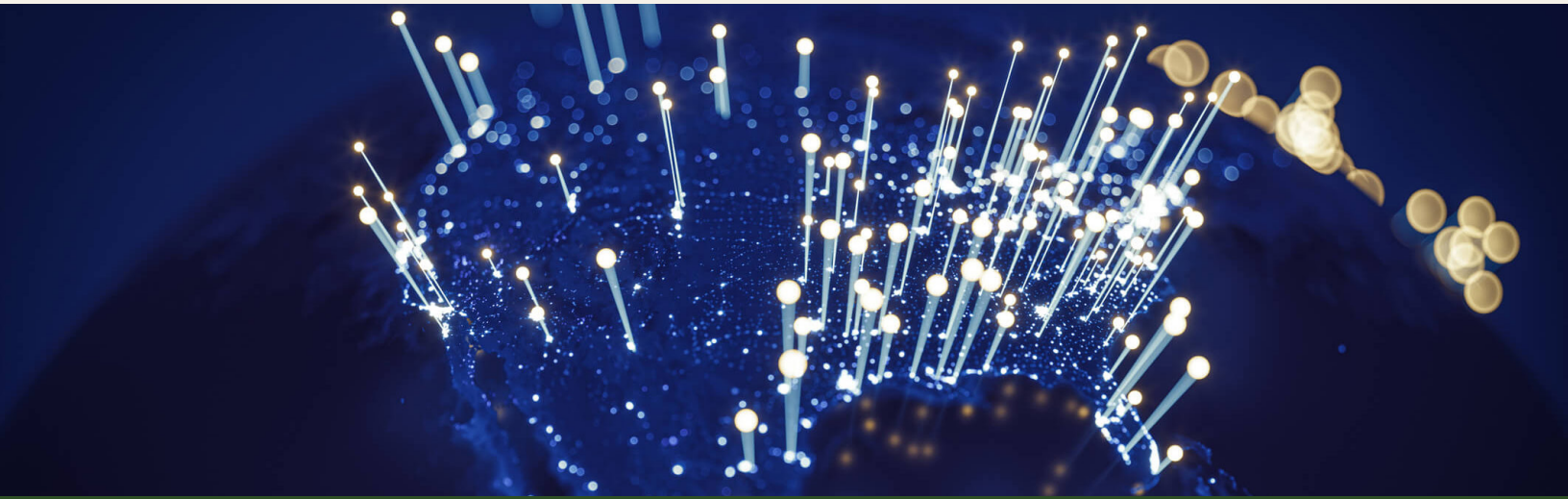
Learn more about CLIA regulations for DTC lab tests in this guide from CMS here.

State laws for DTC lab testing

Another critical consideration for companies is where to market DTC lab tests. Not all states allow consumers direct access to tests without clinician review and authorization. Among states that do allow DAT, there are differences in the types of tests requiring prior clinician review and approval.

To service customers nationwide, companies will need to partner with a clinical network to ensure that all lab tests are reviewed and, where appropriate, ordered compliantly.

Companies like Wheel can provide clinician oversight services for nationwide consumer lab testing. Learn more at wheel.com/companies/labs-diagnostics.



Clinical considerations

Securing a reliable network of board-certified clinicians for test review, authorization for appropriate tests, and results review is a vital step for labs and digital health companies.

Beyond sourcing experienced and qualified healthcare professionals for clinical quality, it's important to ensure the clinician network is independent. In this case, independence refers to a clinician's ability to make unbiased, independent clinical decisions on test appropriateness.

CLINICIAN OVERSIGHT FOR LAB TESTING

Some lab tests and certain states require prior authorization from a clinician to compliantly offer DTC tests. This is called clinician oversight or prescriptive authority for labs.

Clinician oversight includes test review, authorization where appropriate, and results' assessment.

Test review is when a clinician reviews a customer's health information to determine whether a test is clinically appropriate for the individual. If deemed appropriate, the clinician approves the lab test requisition and the customer can complete the test (either at home with a lab kit or at a designated facility).

Test results assessment is when a clinician reviews the lab results for abnormalities or critical values, and when necessary, provides clinical guidance in a follow-up consultation with the customer.

Choosing a clinician oversight partner

Choosing the right partner for clinical services is essential for delivering compliant, competitive, and customer-friendly lab offerings. Poor clinical services can severely impact the brand experience and customer safety, as well as leave companies open to regulatory enforcement.

CLINICIANS SHOULD BE INDEPENDENT AND WHITE LABELED

Working with a vendor that has a patient front door or is partnered with a competitor can put companies at a competitive disadvantage. It's important to ensure clinicians are empowered to act with independence and put patients' needs first. Clinicians should be trained to act as an extension of the companies' team for the most streamlined customer experience.

VENDORS SHOULD ADHERE TO RIGOROUS CLINICAL QUALITY STANDARDS

Clinically appropriate test approvals and reliable test interpretation are imperative for above-board testing services. Third-party clinical partners should retain an in-house medical team for clinical quality oversight and clinician support.

PARTNERS SHOULD DEMONSTRATE THOROUGH REGULATORY COMPLIANCE

Relationships between labs and provider groups are highly regulated and frequent targets of enforcement. Navigating these regulations on a national scale is complicated, and unlawful compliance can seriously jeopardize a business. At a minimum, companies must ensure their clinical partners employ in-house legal counsel experienced in lab and provider group contracting, adhere to HIPAA guidelines, and leverage technology with uncompromised privacy and security controls.

TECHNOLOGY SHOULD BE SIMPLE TO INTEGRATE

Complex and inflexible integrations not only slow time to market but also deliver disjointed and poor customer experiences. A clinical oversight partner should have a technology infrastructure that supports efficient clinical workflows for rapid test turnaround and flexible APIs for seamless data transfer.

Working with Wheel

Wheel provides fast, reliable clinician oversight for direct-to-consumer lab testing that companies and their customers can trust. Our tech-enabled clinical network ensures lab test reviews and consultations are completed in a compliant, efficient, and customer-friendly manner so that companies can scale with confidence.

Direct-to-consumer lab testing with Wheel:

- Nationwide clinician coverage
- Thorough clinical reviews for test appropriateness
- Reliable test interpretation
- Rapid turnaround times
- Safe and medically sound judgment
- Stringent privacy and security compliance
- Consumer-friendly follow-up consultations
- Flexibility to scale up or down quickly
- Simple integration and easy tech

250,000+
Labs processed to date

99%
Guaranteed clinician response times

50+
Nationwide state coverage

Learn more at **wheel.com/companies/labs-diagnostics**.

Rapid scale: 800% increase in monthly test volume in 6 months

Confidential client profile

- Nationwide specialty lab providing large scale, point-of-care diagnostic solutions for healthcare and consumer-facing clients
- Pride themselves on integrity and clinical applicability and appropriateness of lab testing
- Required a tech-enabled clinician network to achieve scale

Client problem

- Existing prescriptive authority partner was slow to respond and inflexible
- New client opportunities required clinical oversight implementation within days, not months
- Stakeholders realized current partnership was biased and unresponsive to their needs

Wheel approach

- Offered a simple, FHIR API integration for rapid launch
- Sourced the right mix of clinicians on an ongoing basis for continuous, scalable coverage
- Provided a white-labeled care team, with clinicians trained in client's brand, technology, and protocols

Results

- Increased test volume by more than **800% over 6 months**
- Achieved **100% adherence** to client's clinical quality metrics and consult SLAs

Rapid scale: 800% increase in monthly test volume in 6 months

What's next?

With the power of Wheel, this client is able to serve new testing programs within as little as two weeks for implementation and launch. Next, the company is embarking on in-home, on-demand diagnostic services with clinical support from Wheel.

"When we found Wheel it was like a breath of fresh air. Your clinicians are amazing with our customers, and we're confident they'll have consistently great experiences. Communication is also important, and Wheel is always available to assist with our needs. We're just so happy."

– Sr. Director of D2C Services - National Lab Company

wheel

Grow your lab services with Wheel.

sales@wheel.com